REMARKS

Applicant respectfully requests reconsideration and allowance of all pending claims.

I. Status of the Claims

Claims 2, 6, 7, 11-13, 18, and 20 are pending in this application. In this Amendment B and Response After RCE, claims 6 and 11 have been amended to more particularly claim the invention. Support for these amendments may be found in previously pending claims 2, 6 and 7. Claims 14-16 have been cancelled. No new matter has been added by way of these amendments.

II. Rejection of Claims under 35 U.S.C. § 112

Claims 2, 6, 7, 11-16, 18, and 20 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. Specifically, the Office has stated that Applicants' claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. In particular, the Office states that the compound as claimed in claim 2 has not been tested and there is no guidance as to how this compound can be used for the claimed methods. Further, the Office states that "the methods of claims 6 and 11 find no possession at the time the invention was filed." Applicants respectfully disagree as claims 2, 6, and 11 are adequately described in the specification as originally filed.

Claim 2 is directed to a method of reducing the level of C-reactive protein (CRP) in an individual subject to a CRP associated inflammatory condition. The method comprises administering to the individual an effective amount of a composition comprising 3-(6-Hydroxy-2,7,8-trimethyl-chroman-2-yl)-propionic acid.

Claim 6, as amended herein, is directed to a method of reducing the level of an inflammatory marker in an individual subject to end-stage renal disease. The method comprises administering to the individual a composition comprising 3-(6-Hydroxy-2,7,8-trimethyl-chroman-2-yl)-propionic acid in an effective amount.

Claim 11, as amended herein, is directed to a method for ameliorating a symptom of an inflammatory condition in an individual subject to an inflammatory condition. The method comprises administering to the individual a composition comprising 3-(6-Hydroxy-2,7,8-trimethyl-chroman-2-yl)-propionic acid, in an amount effective to reduce the level of an inflammatory marker associated with said inflammatory condition.

The description in a patent application as filed is **presumed** to be adequate for purposes of satisfying the written description requirement. (See, e.g., MPEP §2163.04). As a result, the Office has the initial burden of establishing, by a **preponderance of the evidence**, why a person of ordinary skill in the art would not recognize in the application as filed a description of the invention defined by the claims. Applicants respectfully submit the Office has failed to satisfy that burden.

Specifically, as currently pending, the compound for administration in claims 2, 6, and 11 is 3-(6-Hydroxy-2,7,8-trimethyl-chroman-2-yl)-propionic acid. As described in the instant specification, 6-hydroxychromans, such as 3-(6-Hydroxy-2,7,8-trimethyl-chroman-2-yl)-propionic acid, can be isolated as metabolites of tocopherol (see, e.g., US 6,150,402), or can be synthesized (see, e.g., US 2001/0031782), both of these references have been incorporated by reference in their entireties.[1] Additionally, as defined in the specification, "effective amount" refers to an amount sufficient to effect beneficial or desired results; that is, an amount that is sufficient to reduce the inflammatory marker (e.g., CRP).[2] Accordingly, Applicants have adequately described a method of administering 3-(6-Hydroxy-2,7,8-trimethyl-chroman-2-yl)-propionic acid in an amount effective to reduce levels of an inflammatory marker, and more particularly, to reduce levels of CRP.

Furthermore, despite the assertion of the Office, as specifically shown in Example 1A, the claimed compound, 3-(6-Hydroxy-2,7,8-trimethyl-chroman-2-yl)-propionic acid, was effective at reducing CRP levels.[3] Specifically, Example 1A provides exemplary assays for measuring inflammatory reaction in a cell line in order to provide a predictive measure of anti-

[1] Applicants' specification at page 14, lines 1-4.
[2] Applicants' specification at page 6, lines 1-6.
[3] Applicants' specification at pages 17-18, Example 1A.

inflammatory activity of compositions of the present invention; that is, Example 1A provides a method for determining if the compositions of the present invention, and specifically if a composition including either 3-(6-Hydroxy-2,7,8-trimethyl-chroman-2-yl)-propionic acid methyl ester or **3-(6-Hydroxy-2,7,8-trimethyl-chroman-2-yl)-propionic acid** could effectively reduce the level of C-reactive protein (CRP) in an individual subject to a CRP associated inflammatory condition. As shown on page 18, lines 27-31, 3-(6-Hydroxy-2,7,8-trimethyl-chroman-2-yl)-propionic acid, at an EC_{50} of between about 40 to about 60 μM, was effective at reducing CRP levels.

Based on the foregoing, Applicants submit that the language of claims 2, 6, and 11 is clearly supported by the specification of the application as filed. Applicants further submit that one of ordinary skill in the art, which by the Office's own admission is a person having a high degree of skill and knowledge, would recognize that Applicants were in possession of the subject matter of claims 2, 6, and 11 as of the filing date of the present application. Furthermore, in view of the high degree of skill and knowledge in the art, Applicants respectfully disagree with the Office's assertion that the possible compounds cover a large number of compounds and that the description is merely an indication of Applicants' goals. (See the Office action at page 4.) To the contrary, the requirements of claims 2, 6, and 11, taken as a whole, provide both function and structure. Specifically, the structural and functional details are provided for 3-(6-Hydroxy-2,7,8-trimethyl-chroman-2-yl)-propionic acid for reducing the level of an inflammatory marker.

In view of the foregoing, Applicants respectfully submit that claims 2, 6, and 11 satisfy the written description requirement of 35 U.S.C. 112, first paragraph. Reconsideration and withdrawal of the present rejection is therefore respectfully requested.

Inasmuch as claims 7, 12, 13, 18, and 20 directly or indirectly depend from claims 2, 6, and/or 11, it is submitted that these claims satisfy the written description requirement for at least the same reasons as set forth with respect to claims 2, 6, and 11, as well as the other requirements recited therein. In particular, it is submitted that (i) claims 12 and 18, which further specify the inflammatory marker and (ii) claim 13, which further specifies the inflammatory condition, satisfy the written description requirement, in view of the specificity recited therein.

CONCLUSION

In view of the foregoing, Applicant respectfully requests favorable reconsideration and allowance of all pending claims.

The Commissioner is hereby authorized to charge Deposit Account 01-2384 in the name of Armstrong Teasdale LLP for any fees due for the submission of this Amendment B and Response After RCE, including the fee for the Request for Continued Examination being filed simultaneously herewith.

Respectfully submitted,

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Via EFS